

Appl. No. 10/727,457
Att. Docket No. 8601MC
Reply dated 12/14/2004
Not of Non-Compliance dated 12/02/2004
Customer No. 27752

AMENDMENTS TO THE SPECIFICATION

The Office Action asserts that on page 1, the title of the invention fails to correspond with that given in the declaration. Applicants refer Examiner to the new declaration included herewith, which reflects the amended title of the invention.

Applicants request that the specification be amended as follows:

Please remove bold-face type and underlining from the title. Please remove underlining from the section headings on pages 1 and 3.

Please delete the paragraph appearing on page 2, line 13 and insert the amended paragraph to read:

--The flow control layer according to the invention may comprise an apertured film, non-woven material, non-woven with microfibers, woven material, meltblown structure or mixtures of these materials. Advantageously, the flow control layer comprises CLIFF™ (Cloth Like Formed Film) hydroapertured film of LDPE with 1% ATMER™ (anti-static agent) ~~Atmer~~ and 0.8 gsm (grams per square meter) silicone coating (Tredegar Corp.).—

Please delete the paragraph appearing on page 2, lines 18 and insert the amended paragraph to read:

--The fluid storage layer according to the invention may comprise ~~batting, sponge or foam~~ batting, sponge, foam and combinations thereof. Advantageously, ~~[[it]]~~ the batting may itself comprise viscose fibers. Additionally or alternatively, the fluid storage layer may comprise a dosing reservoir capable of containing and dispensing fluid. Advantageously, the dosing reservoir is rupturable, although other methods known to the skilled person may be used to facilitate release of the fluid.--

Please delete the paragraph appearing on page 2, line 25 and insert the amended paragraph to read:

--Advantageously, the disposable applicator according to the invention may comprise a skin contact layer located on the opposite side of the flow

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control layer to the fluid storage layer and/or a hand contact layer located on the opposite side of the fluid impermeable layer to the fluid storage layer. The hand contact layer and the skin contact layer may comprise identical or different materials selected from woven materials, non-woven materials, natural or ~~synthetic~~ synthetic sponge,, polymeric mesh sponge, paper substrate, polymeric porous foam, collagen sheets, polymeric scrim and mixtures of these materials.--

Please delete the paragraph appearing on page 2, line 32 and insert the amended paragraph to read:

--Advantageously, the disposable applicator according to the present invention may additionally comprise a temperature-change element for heating or cooling the substrate, the fluid or both. The temperature-change element may provide heat derived from a chemical reaction, heat of solution, crystallisation, an electrical heating element or a mixture of these. Alternatively, the temperature-change element may be a cooling element and cooling may be provided by an endothermic chemical reaction, an electrical cooling element or a mixture of these. According to a specific embodiment, the disposable applicator may additionally define a catalyst chamber containing a catalyst and a separate reactant chamber containing a reactant, the chambers being rupturable so that on rupture their respective contents mix to initiate the reaction and generate the temperature change.--

Please delete the paragraph appearing on page 3, line 8 and insert the amended paragraph to read:

--According to a second aspect of the invention, a method of applying a fluid to skin is presented comprising the steps of holding the disposable applicator ~~according to any one of the preceding claims~~ described in any of the above aspects, and wiping it onto the skin.--

Please delete the paragraph appearing on page 3, line 16 and insert the amended paragraph to read:

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--Figs. 1A, 1B and 2 illustrate embodiments of the present invention comprising a temperature-change element as defined hereinbelow, which provides heating or cooling to the disposable fluid applicator.--

Please delete the paragraph appearing on page 3, line 25 and insert the amended paragraph to read:

--As used herein, "disposable" is used in its ordinary sense to mean an applicator that is disposed or discarded after a limited number of usage events, preferably less than 25, more preferably less than about 10, and most preferably less than about 2 entire usage events.--

Please delete the paragraph appearing on page 5, line 23 and insert the amended paragraph to read:

--Nonwoven materials made from synthetic fibers may be obtained from a wide variety of commercial sources. Examples of suitable nonwoven layer materials useful herein are described in WO98/18444 and include HEF (hydro-entangled fabric) 40-047, an apertured hydroentangled material containing about 50% rayon and 50% polyester, and having a basis weight of about 51 grams per square metre (gsm), available from Veratec, Inc., Walpole, MA; ; Novonet^R 149-616, a thermo-bonded grid patterned material containing about 100% polypropylene, and having a basis weight of about 60 gsm, available from Vcratec, Inc., Walpole, MA; and HEF NubtexTM 149-801, a nubbed, apertured hydroentangled material, containing about 100% polyester, and having a basis weight of about 84 gsm, available from Veratec, Inc. Walpole, MA.--

Please delete the paragraph appearing on page 6, line 13 and insert the amended paragraph to read:

--In another embodiment, an apertured laminate web may be employed having first and second extensible webs being joined at a plurality of discrete bond sites and a third material disposed between the first and second nonwoven webs. The first and second nonwoven webs are in fluid communication via the apertures and have distinct regions being

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differentiated by at least one property selected from the group consisting of basis weight, fiber orientation, thickness, and density.--

Please delete the paragraph appearing on page 6, line 21 and insert the amended paragraph to read:

--Paper substrates made from natural materials consist of webs or sheets most commonly formed on a fine wire screen from a liquid suspension of the fibers. ~~See See Hampel et al., The Encyclopedia of Chemistry The Encyclopedia of Chemistry, third edition, 1973, 3rd Ed., pp. 793-795 (1973); The Encyclopedia Americana The Encyclopedia Americana, vol. 21, pp. 376-383 (1984); and G.A. Smook, Handbook of Pulp and Paper Technologies Handbook of Pulp and Paper Technologies, Technical Association for the Pulp and Paper Industry (1986).~~ Paper substrates made from natural materials useful in the present invention can be obtained from a wide variety of commercial sources. Suitable commercially available paper substrates useful herein include "Kimwipes EX-L" available from Kimberley-Clark Corp., Roswell, GA, USA; Airtex^R, an embossed airlaid cellulosic layer having a base weight of about 85 gsm, available from James River, Green Bay, WI; and Walkisoft^R, an embossed airlaid cellulosic having a base weight of about 90 gsm, available from Walkisoft U.S.A., Mount Holly, NC.—

Please delete the paragraph appearing on page 7, line 3 and insert the amended paragraph to read:

--Preferably, the skin contact layer is selected from Novonet 149-616, Corovin LLDPE (linear low-density polyethylene), SAN, ~~PP/Rayon~~ Polypropylene (PP)/Rayon mixtures supplied by Suominen and DEC. Even more preferably the skin contact layer comprises Corovin LLDPE, PP/Rayon mixtures from Suominen and DEC. More preferably, the skin contact layer comprises Corovin LLDPE 60gsm, spunbonded.—

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Please delete the paragraph appearing on page 7, line 26 and insert the amended paragraph to read:

--A formed-film substrate useful herein is an apertured formed film - a resilient, 3-dimensional web exhibiting a fiber-like appearance and tactile impression, comprising a fluid-impervious plastic material, with said web having a multiplicity of apertures, the apertures being defined by a multiplicity of intersecting fiberlike elements, as described in US 4,342,314. The sheet materials described in US 4,342,314 can be prepared using hydrophobic plastics such as polyethylene, polypropylene, PVC, and the like, and are well-known for use in absorbent products such as catamenials. An example of such a material is the formed film described in the above patent and marketed on sanitary napkins by The Procter and Gamble Company as "DRI-WEAVE™". Additionally, such materials may be surface treated to reduce their hydrophobicity. An additional example of a formed-film substrate suitable for use in this application is "CLIFF™". (Cloth Like Formed Film) Hydroapertured formed film, LDPE (low-density polyethylene) with 1% ATMER™ (Uniquema) and 0.8gsm Si coating.--

Please delete the paragraph appearing on page 8, line 4 and insert the amended paragraph to read:

--Preferably, the flow control layer is selected from DRI-WEAVE™ and CLIFF™ hydroapertured formed film, LDPE with 1% Atmer 100 and 0.8gsm Si coating. Most preferably the flow control layer is selected from CLIFF hydroapertured formed film, LDPE with 1% Atmer 100 and 0.8gsm Si coating.--

Please delete the paragraph appearing on page 8, line 13 and insert the amended paragraph to read:

--Batting useful in the fluid storage layer of the present invention is preferably lofty. As used herein, "lofty" means that the layer has a density of from about 0.00005 g/cm³ to about 0.1 g/cm³, preferably from about

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0.001 g/cm³ to about 0.09 g/cm³ and a thickness of from about 0.1 cm (0.04 inches) to about 5cm (2 inches) at 5 gms/in².--

Please delete the paragraph appearing on page 9, line 7 and insert the amended paragraph to read:

--For the core-sheath fibers, preferably, the cores comprise materials selected from the group consisting of polyesters, polyolefins having a T_g (glass transition phase) of at least about 10°C higher than the sheath material, and combinations thereof. Conversely, the sheaths of the bicomponent fibers preferably comprise materials selected from the group consisting of polyolefins having a T_g of at least about 10°C lower than the core material, polyesters polyolefins having a T_g of at least about 10°C lower than the core material, and combinations thereof.--

Please delete the paragraph appearing on page 10, line 17 and insert the amended paragraph to read:

--One important aspect of the dosing reservoir, is its ability to rupture or otherwise dispense a contained fluid when "activated" by the user, and yet, resist premature dispensing during manufacture, packaging, and shipment, thereby preserving the quality and quantity fluid until the time of use. The dosing reservoir may be made from a flexible film sealed around the perimeter by a permeable membrane. In a non-limiting example, the dosing reservoir can be formed from a single material partially or completely folded onto itself. The folded material may then be heat sealed on at least three sides. The interior volume or volumes can then contain the fluid. The dosing reservoir may also be made by sealing two films to each other along a common perimeter. The flexible film can include a sealant on one or both sides and can include a higher melting support structure such as a thin layer of PET (polyethylene terephthalate), nylon, or polypropylene. Seals that create the dosing reservoir can be both permanent seals, such as such as lock-up or welded seals, or have a rupturable or frangible capacity.--

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Please delete the paragraph appearing on page 12, line 19 and insert the amended paragraph to read:

--The hand contact layer may additionally or alternatively comprise a tacky or friction-enhancing material to ease handling of the applicator. Suitable materials that can be used as the friction-enhancing elements include rubber, thermoplastic elastomers (e.g., KRATON® produced by Shell Chemical Company), polyolefins with ethylene vinyl acetate or alpha-olefin copolymers, and polyolefin plastomers (e.g., Affinity® AFFINITY® produced by Dow Chemical of Midland, MI and ~~Exact~~ EXACT® polyolefin plastomers produced by Exxon Chemical of Houston, TX).--

Please delete the paragraph appearing on page 14, line 3 and insert the amended paragraph to read:

--With reference to ~~Fig. 1~~ Figs. 1A and 1B, an embodiment of the present invention is illustrated comprising a temperature-change element. In this embodiment, the applicator (306) consists of four layers of material: the top layer is the flow control layer (332) which comprises a membrane through which product is transferred from the applicator to the skin. Flow control layer (332) is permanently sealed around the perimeter of the applicator to fluid impermeable layer (308).--

Please delete the paragraph appearing on page 14, line 8 and insert the amended paragraph to read:

--A further layer (302) (also an impermeable film) is sealed on both sides. This layer has a hole, (304) of about 5 mm diameter punched in it.

Please delete the paragraph appearing on page 14, line 10 and insert the amended paragraph to read:

--The impermeable layer (308) and the further layer (302) are permanently sealed around the perimeter of the applicator. Three additional permanent seals are made in areas (310), (312) and (314). These seals, in conjunction with the perimeter seal, divide the area defined as between the fluid

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impermeable and further layers and interior to the perimeter seal, into three zones. These zones are identified as (316), (318), and (320). In the current embodiment, zone (320) is a chamber (358) containing a catalyst, zone (318) is a chamber containing a reactant, and zone (316) is a chamber containing fluid (330) (the fluid storage layer). The interior permanent seals are angled to create stress concentrators that aid in the activation of the frangible seals (322) and (324).--

Please delete the paragraph appearing on page 14, line 25 and insert the amended paragraph to read:

--With reference to Fig. 2, a further embodiment of the present invention (366) is illustrated comprising a temperature-change element (364). This embodiment comprises a skin contact layer (350) adjacent to a flow control layer (332), which comprises a membrane. The skin contact layer (350) and the flow control layer can also be integrally formed. Fluid control layer (332) is permanently sealed around the perimeter to further layer (356). Further layer (356) is a film having multiple polymer layers; it is important that there is sealable polymer content on both surfaces of the film to allow for thermal bonding of said film and that it be impermeable. The void space created between the flow control membrane (332) and further layer (356) is the fluid (330) storage layer ~~(330)~~. Fluid impermeable layer (352) is permanently sealed (354) around the perimeter (362) of the temperature-changing element (364) to further layer (356). The fluid impermeable layer (352) is also sealable on both surfaces.--

Please delete the paragraph appearing on page 15, line 10 and insert the amended paragraph to read:

--The entire construction may have a hand containment strap (370) or hood added to create a finger mitt embodiment.--

Please delete the paragraph appearing on page 16, line 30 and insert the amended paragraph to read:

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--Anti-inflammatory agents useful herein include steroids such as hydrocortisone; non-steroidal anti-inflammatory drugs (NSAIDS) such as ibuprofen; panthenol and ether and ester derivatives thereof e.g. panthenol ethyl ether, panthenyl triacetate; pantothenic acid and salt and ester derivatives thereof, especially calcium pantothenate; aloe vera, bisabolol, allantoin and compounds of the liquorice (the plant genus/species ~~Glycyrrhiza glabra~~ Glycyrrhiza glabra) family, including glycyrrhetic acid, glycyrrhizic acid, and derivatives thereof e.g. salts such as ammonium glycyrrhizinate and esters such as stearyl glycyrrhetinate. Particularly preferred herein are panthenol, pantothenic acid and their ether, ester or salt derivatives and mixtures thereof; suitable levels are from about 0.1 to about 5%, preferably from about 0.5 to about 3%. Panthenol is especially preferred. Panthenol additionally provides short-term benefits such as humectancy.--

Please delete the paragraph appearing on page 18, line 21 and insert the amended paragraph to read:

--The present fluids may comprise a wide variety of emollients. Sagarin, ~~Cosmetics, Science and Technology~~ Cosmetics, Science and Technology, 2nd Edition, Vol. 1, pp. 32-43 (1972) contains numerous examples of materials suitable as an emollient. Illustrative examples of emollients include:--

Please delete the paragraph appearing on page 22, line 21 and insert the amended paragraph to read:

--The present fluids may contain an emulsifier and/or surfactant, generally to help disperse and suspend the discontinuous phase within the continuous phase, in the case that the fluid is an emulsion. A surfactant may also be useful if the product is intended for skin cleansing. Known or conventional surfactants can be used in the composition, provided that the selected agent is chemically and physically compatible with essential components of the composition, and provides the desired characteristics. Suitable surfactants include non-ionic, anionic, amphoteric and zwitterionic surfactants such as those known in the art, for example from

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McCutcheon's, ~~Detergents and Emulsifiers~~ *Detergents and Emulsifiers*,
North American Edition (1986) published by Allured Publishing
Corporation.—

Please delete the paragraph appearing on page 23, line 6 and insert the amended
paragraph to read:

--The present fluids may comprise a thickening agent selected from
carboxylic acid polymers, crosslinked polyacrylates, polyacrylamides,
xanthan gum and mixtures thereof, more preferably selected
polyacrylamide polymers, xanthan gum and mixtures thereof. Preferred
polyacrylamides are predispersed in a water-immiscible solvent such as
mineral oil and the like, containing a surfactant (HLB, or hydrophilic
lipophilic balance, of from about 7 to about 10) which helps to facilitate
water dispersibility of the polyacrylamide. Most preferred for use herein
is the non-ionic polymer under the CTFA designation: polyacrylamide and
isoparaffin and laureth-7, available under the trade name Sepigel 305 from
Seppic Corporation.--

Please delete the paragraph appearing on page 24, line 14 and insert the amended
paragraph to read:

--The present fluids may also comprise pigments and other particulates
which may provide visual benefits. Pigments suitable for use in the
compositions of the present invention can be organic and/or inorganic.
Also included within the term pigment are materials having a low colour
or lustre such as matte finishing agents, and also light scattering agents.
Examples of suitable pigments are iron oxides, acylglutamate iron oxides,
titanium dioxide, ultramarine blue, D&C dyes, carmine, and mixtures
thereof. Depending upon the type of composition, a mixture of pigments
will normally be used. Other particulates useful herein include
~~Orgasol~~ORGASOL®, ~~Nylon-Poly~~NYLON POLY®, ~~Dry-Flu Plus~~DRY-
FLO PLUS® polymethylsilsesquioxane and dimethicone / vinyl
dimethicone cross polymer.--

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Please delete the paragraph appearing on page 24, line 22 and insert the amended paragraph to read:

The present fluids may also comprise a crosslinked organopolysiloxane elastomer. The crosslinked organopolysiloxane elastomers can be either partially or completely crosslinked, and can be selected from the group comprising of emulsifying and non-emulsifying elastomers. Emulsifying elastomers are essential for water in silicone elastomeric formulations. Preferred crosslinked organopolysiloxane elastomers are selected from dimethicone/vinyl dimethicone copolymers and organopolysiloxanes containing a polyoxyethylenated and/or polyoxypropylenated chain. Dimethicone/vinyl dimethicone copolymers are supplied by a variety of suppliers including Dow Corning (DC 9040 and DC 9041), General Electric (SFE 839), Shin Etsu (KSG-15, 16, 18 [dimethicone /phenyl vinyl dimethicone crosspolymer]), and Grant Industries (Gransil™ line of materials), and lauryl dimethicone/vinyl dimethicone crosspolymers supplied by Shin Etsu (KSG-15, 16, 18™ [dimethicone /phenyl vinyl dimethicone crosspolymer]), and Grant Industries (~~Gransil~~GRANISIL™ line of materials), and KSG™ lauryl dimethicone/vinyl dimethicone crosspolymers supplied by Shin Etsu (e.g., KSG-31, KSG-32, KSG-41, KSG-42, KSG-43, and KSG-44). Organopolysiloxanes containing a polyoxyethylenated and/or polyoxypropylenated chain are marketed by Shin-Etsu under the name KSG21, KSG31, KSG31x and KSG32 or by Dow Corning under the name DC 9011™.--

Please delete the paragraph appearing on page 25, line 7 and insert the amended paragraph to read:

--Preferred vehicles contain a dermatologically acceptable, hydrophilic diluent. Suitable hydrophilic diluents include water, organic hydrophilic diluents such as C₁ - C₄ monohydric alcohols and low molecular weight glycols and polyols, including propylene glycol, polyethylene glycol (e.g. of MW 200-600), polypropylene glycol (e.g. of MW 425-2025), glycerol, butylene glycol, 1,2,4-butanetriol, sorbitol esters, 1,2,6-hexanetriol,

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ethanol, iso-propanol, sorbitol esters, ethoxylated ethers, propoxylated ethers and combinations thereof, where MW means the average molecular weight. The diluent is preferably liquid. Water is an especially preferred diluent.—